



Speakers



Dr Katrin Buss (invited)
Bonn



Marcel Dörkes
Eurofins BioPharma



Dr Armin Hauk
Sartorius Stedim Biotech



Dr Dennis Jenke
Triad Scientific
Solutions



Dr Ana Kuschel
West Pharmaceutical
Services



Dr Andreas Nixdorf
SGS Institut Fresenius



Gaby Reckzügel
Boehringer Ingelheim
Pharma

Extractables & Leachables

Challenges and Solutions for Packaging / Devices & Single Use Systems



Live Online Training on 06/07 May 2025



Image: Agilent

Highlights

- Current Regulatory Requirements
- Practical Approaches for E&L Testing
- Evaluation of E&L Data
- Toxicological Assessment
- Leachable Studies for SUS and Devices
- How to use prior Knowledge and IT Solutions

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Objectives

In this Live Online Training you will learn

- How to evaluate potential risk factors associated with leaching substances
- How to design extractables studies as part of material qualification and selection
- How to control and manage the life cycle of E&Ls
- How to assess the toxicological risks of E&Ls

You will also get an update on requirements and expectations of E&L testing and risk management from a regulatory perspective.

Over the last years, the requirements on the assessment of substances that could leach into the drug product in the course of its life cycle have increased considerably.

The specific kind of extractable/leachable can vary from organic oligomers and catalyst residues to heavy metals – to name a few. Due to the resulting complexity, it is very important to consider the potential risk factors associated with leaching substances already at a very early stage in process development. Therefore, the ICH is currently working on a new ICH Q3E Guideline for Extractables and Leachables (E&Ls) to “assist both applicants and regulators by providing focus on critical aspects, and improving transparency in requirements for medicinal products including drug delivery device components”.

Packaging materials have been in the focus of such investigations for a long time as the contact time between drug product and packaging material is rather long. Recently, particular attention was paid to devices and equipment used in the production process, e.g. filters, bags, tubes.

Target Audience

The course is designed for personnel of pharmaceutical companies and their suppliers who

- are responsible for setting up E&L studies and E&L testing.
- work in quality control of packaging materials.
- specify and select polymeric, glass and rubber materials, devices and Single Use Equipment in process development and manufacturing.
- develop material sourcing strategies.

Programme

Day 1

Introduction to Plastics used in Medical Applications

- Classification of plastics
- Physical and chemical characteristics
- Different types of additives in plastics

Regulatory Perspective (Authority View)

- Applicable Guidelines (EU)
- Update on ICH Q3E
- Experiences in regulatory submissions

Regulatory and Scientific Perspective (Industry View)

- Regulatory requirements of EMA and US-FDA
- Compendial requirements and foodstuff regulations
- PQRI recommendations and ICH Guidelines: Safety Thresholds and Permitted Daily Exposure
- USP <1663>, <1664>: Best Practices for E&L testing
- Scientific Aspects




Q&A Session 1


How to Prepare a Successful E&L Study

- E&L Study organization for finished packaging's, timely planning
- Extractables study designs as part of material qualification and selection
- Selection of extraction conditions and methods
- Identification categories, trustable identification,
- Semi-quantitation, analytical uncertainty
- Analytical methods, target analysis or screening or both
- Analytical sensitivity adjustment, correlation with analytical evaluation threshold
- Impact of sterilization methods on materials chemical composition

Strategies for Complex Formulated Drug Products

- Analytical method requirements, validation of Leachables analytical methods
- Development of Leachables strategies based on Extractable profile and toxicological report
- How to deal with trustable and poorly characterized chemical profiles
- How to establish the “chemical link” between Extractables & Leachables
- Leachables observed only in Leachables study but not in the Extractables Study: What to do?
- OOS case

 „The leachables profile should also be determined for compendial plastics and rubber container closure components.“
EMA Guideline on Pharmaceutical quality of inhalation and nasal products

 „For plastic material used for container closure systems for active substances or medicinal products, toxicological data should be provided for extractables and leachables, depending on their level and chemical structure.“
Eudralex Volume 3 Guideline on Plastic Immediate Packaging Materials

Analytical Challenges and Solutions for Extractables & Leachables

- Essential Analytical Expectations for E&L Studies
- Qualitative Aspects of Extractables and Leachables
- Identification and Good Identification Practices
- Quantitative Aspects of Extractables and Leachables
- Analytical Uncertainty
- When to Quantify –The Analytical Evaluation Threshold (AET)
- How to Quantify –Good Quantitation Practices

Q&A Session 2

Day 2

Elastomeric Closures in E&L Assessment

- Composition of Elastomers used for Pharmaceutical Applications
- Discussion Material Composition and Extractables (Potential Extractable List)
- Approaches to minimize Extractables/ Leachables from Elastomeric Closures
- Case Study presentation

Practical Examples for E&L Testing in Medical Devices

- Key aspects of ISO 10993-1 and ISO 10993-18 for E&L testing of medical devices
- General procedures, challenges, and pitfalls
- Case studies and practical examples


Toxicological Assessment of E&Ls in Medical Devices


- Key aspects of ISO 10993-17 for the toxicological evaluation
- General procedures, challenges, and pitfalls
- Case Studies for different assessment procedures

Q&A Session 3

Control and Life Cycle Management of E&Ls

- Batch-to-batch consistency in composition and purity of packaging components
- Acceptance criteria for Extractables/Leachables
- Quality agreements with suppliers
- Change Management

 “All surfaces that come in contact with products shall be clean and free of surface solids, leachable contaminants, and other materials that will hasten the deterioration of the product or otherwise render it less suitable for the intended use.” CFR21, 600.11 (b)

 “All final containers and closures shall be clean and free of surface solids, leachable contaminants and other materials that will hasten the deterioration of the product or otherwise render it less suitable for the intended use.” 21CFR, 600.11 (h)

E&Ls for SUS as Elements of Process Qualification/ Validation and Safety Assessment

- Single-Use process equipment (e.g. filters, bags)
- Risk-based evaluation and testing strategies
- Influence of leachables on:
 - biopharmaceutical process performance
 - the stability of biopharmaceuticals
 - the analytics of biopharmaceuticals

Simplified E&L Assessment using prior Knowledge and IT Solutions

- Prediction of extractables profiles for SUS of different sizes and complex assemblies
- Calculation of exposure data, with a subsequent automated safety-assessment; including a discussion of deviations and propagation of deviations
- Equivalence study of extractables profiles from an SU assembly before and after a component change, including the evaluation of the impact on the safety assessment
- Using the system to extrapolate extractables data to USP <665> conditions for a safety assessment of a large volume injectable drug product

Q&A Session 4

Speakers



Dr Katrin Buss
Quality Assessor, Bonn, Germany (invited)

Katrin Buss is a pharmacist and worked from 2001-2004 as Scientific Project Manager at Memorec/Miltenyi Biotec. Since 2005 she is quality assessor in the department "Pharmaceutical Biotechnology" at the BfArM (since April 2023 Head of the department). She is member of the ICH Q3E EWG on Assessment and Control of Extractables and Leachables.



Marcel Dörkes
Eurofins BioPharma, Germany

Marcel has been working in the field of evaluating the biological safety of medical devices since February 2018 and is now Head of Medical Device Consulting. Marcel Dörkes' expertise includes the biological safety assessment of medical devices and related toxicological issues including strategy planning, chemical characterization procedures and overall biological risk assessments.



Dr Armin Hauk
Sartorius Stedim Biotech GmbH, Germany

Armin has a position as Principal Scientist at Sartorius Stedim Biotech GmbH since 2016. Before that he was over 20 years active as head of laboratories for organic trace-analysis and GLP & GMP analytics in Ciba-Geigy, and Ciba Specialty Chemicals. For Intertek, Switzerland he worked as consultant and Qualified Person (QP). Armin is a lecturer and trainer in E&L at conferences and seminars and is a member of various industry consortia (BPSA, BPOG, DECHEMA, and MIT BioMan). He is chairperson of the Pharmacopeia expert group 16 in the European Directorate for Quality of Medicine (EDQM).



Dr Dennis Jenke
Triad Scientific Solutions, USA

Dennis got a PhD from Montana State University Bozeman in Analytical Chemistry. He worked over 33 years for Baxter. His primary responsibilities include the development, validation and application of diverse analytical strategies and methods for the discovery, identification and quantification of trace constituents in pharmaceutically relevant solutions and samples. Currently he is Chief Executive Scientist at Triad Scientific Solutions, Inc. which is his own consulting firm.



Dr Ana Marques Kuschel
West Pharmaceutical Deutschland GmbH & Co. KG, Germany

As Principal Scientific Affairs Europe, Ana is providing technical support relating to West's packaging components and delivery systems for injectable drugs and healthcare products, as well as bridging scientific information through industry outreach. This is complementing her previous role as Manager Material Development, where she worked on both existing and new rubber formulations.

Speakers



Dr Andreas Nixdorf
SGS Institut Fresenius GmbH, Germany

Dr Nixdorf studied organic chemistry at the University of Bielefeld. 2007 to 2010 he joined SGS Institute Fresenius GmbH with focus on development of analytical methods, method transfer and validation. He introduced Extractables & Leachables services at SGS. He troubleshoots and directs the resolution of QC method issues by fostering effective interdepartmental and cross-functional partnerships with clients from pharmaceutical industry.



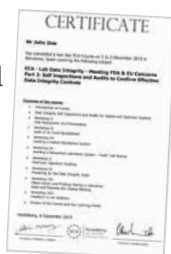
Gaby Reckzügel
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Gaby Reckzügel is leading the Center of Expertise for Extractables & Leachables within Development at Boehringer. Here she is involved in the selection of materials and is responsible for chemical characterization of packaging, device, and process equipment components and for leachables studies. She is in charge of development and validation of routine quality control methods.

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Date of the Live Online Training

Tuesday, 06 May 2025, 09.00 – approx. 17.30 h
Wednesday, 07 May 2025, 09.00 – approx. 17.30 h
All times mentioned are CEST.

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Fees (per delegate, plus VAT)

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Registration

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The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

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Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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